



M3323N

Certified/Return Receipt Requested

December 27, 1999

Food and Drug Administration
Kansas City District Office
11830 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTERBruce C. Rohde, Chief Executive
Officer
ConAgra, Inc.
One ConAgra Drive
Omaha, NE 68102

KAN #2000-007

Dear Mr. Rohde:

An inspection of your medicated feed mill operation known as ConAgra Poultry Company, 6410 SW Hollowell Road, Columbus, Kansas, by an inspector with the Kansas Department of Agriculture, on November 17, 1999, found significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include, but are not limited to the following: 1) failure of the Master Record Files to contain manufacturing instructions, mixing steps or control directions; 2) failure to investigate and document a 22 pound shortage of the medicated premix Avatec which occurred on 11-15 & 16-99; 3) failure of the daily inventory drug record to indicate the specific batches or production runs of medicated feeds in which each drug was used.

In addition, you are manufacturing various medicated turkey feeds using medicated articles or combinations thereof, which are not approved for consumption by turkeys. This causes the medicated feeds to be adulterated within the meaning of Section 501(a)(6) in that the medicated feed contains a new animal drug, causing the feed to be unsafe within the meaning of Section 512.

The medicated feeds *Breeder Selector* (14-4501), *Turkey Fattener* (16-6601) and *Turkey Marketer* (16-6701), contain the medicated article bacitracin zinc which is approved for use in growing turkeys [21 CFR 558.78(d)(1)(i)]. These medicated feeds do not appear to be the type consumed by growing age turkeys.

The medicated feeds *Turkey Prestarter* (16-6101), *Turkey Starter* (16-6201), *Turkey Grower* (16-6301), *Turkey Developer* (16-6401) and *Turkey Finisher* (16-6501), contains the medicated articles virginiamycin and lasalacid in combination. These medicated articles are approved for use in combination for broiler or fryer chickens only [21 CFR 558.311(e)(1)(v)].

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

We also received a letter dated December 6, 1999 (unsigned) which is a response to the observations listed on the Form FDA 483. This response was taken into consideration during the preparation of this letter.

At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with Bruce Zidwell, Mill Manager. This form is a comprehensive listing of the inspector's observations of deviations found during the inspection. A copy is enclosed for your information.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.)

Based on the results of the November 17 inspection, evaluated together with the evidence before FDA when your license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Bruce Zidwell, Mill Manager
ConAgra Poultry Co.
6410 SW Hollowell Road
Columbus, KS 66725